UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,341	04/14/2004	Gary W. Guenst	P0010073.00	5392

27581 7590 08/11/2009

MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	PAPER NUMBER
3773	
MAIL DATE	DELIVERY MODE
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,341	GUENST, GARY W.	
	Examiner	Art Unit	
	MELANIE TYSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 32-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 32-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 May 2009 has been entered. Claims 21-31 remain cancelled.

Election/Restrictions

Under further consideration, the means disclosed for delivering a pressurized blood source all appear to be obvious variants. Therefore, the restriction requirement made 08 December 2006 between species I depicted in Figure 7, and species II depicted in Figure 8 is hereby **WITHDRAWN**. All pending claims have been examined.

Response to Arguments

Applicant's arguments with respect to claims 1-20 and 32-42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claims 8-17 and 39-41 are objected to because of the following informalities: the claims recite "the oxygenated fluid," but the independent claims recite "the oxygenated liquid." Replace "fluid" with --liquid-- where appropriate. Also, in claim 9 insert --the-- between "in which" and "oxygenated." Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites "the method of claim 1, further comprising retracting the tubular member within the conduit." This limitation is confusing, since claim 1 already recites the step of "withdrawing the tubular member through the conduit."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gifford, III et al. (U.S. Patent No. 5,695,504). Gifford discloses a method of joining a blood conduit to a blood vessel (see entire document) comprising the steps of making an incision (700) in the blood vessel wall (682), inserting a tubular member (691) into a conduit (graft vessel 254), advancing the tubular member distal region (693) through the incision, expanding the tubular member distal region (the inflatable balloons 696 and 697) radially outward, performing the anastomosis (or "fixedly joining the conduit distal region to the vessel wall") near the incision while

providing an oxygenated liquid flow from an outlet (694) of the tubular member disposed within the conduit and into the blood vessel, and after performing the anastomosis (or "fixedly joining the conduit to the vessel") withdrawing the tubular member through the conduit (for example, see column 65, line 58 through column 66, line 22, and Figure 54 for further details). Gifford also discloses the anastomosis can be performed using any of the methods described in the disclosure, in which Gifford discloses anastomosis procedures that may include suturing the conduit to the vessel wall (for example, either the use of sutured anastomosis or stapled anastomosis techniques is described in column 68, lines 6-14). Gifford further discloses the blood vessel may be a coronary artery, the aorta, or any other vessel (for example, see column 9, lines 32-34), the conduit may be a saphenous vein or an internal mammary artery (for example, see column 66, line 64 through column 67, line 7), the oxygenated fluid may include blood or a non-blood oxygenated carrying substance (for example, see column 66, lines 8-13), and the blood oxygenated fluid may include blood supplied from the patient's femoral artery (for example, in the procedure in which the blood vessel is the femoral artery) or aorta (for example, in the procedure in which the blood vessel is the aorta).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 14-17, 32-38, and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al.

Regarding claim 32, Gifford discloses that end-to-end anastomosis procedures are well known and suggests that the device disclosed is suitable for both end-to-side and end-to-end anastomosis procedures (for example, see background of the invention). To perform the steps of advancing the tubular member through the blood vessel proximal end and fixedly joining the conduit distal region to the vessel wall near the blood vessel proximal end would have been obvious to one having ordinary skill in the art at the time the invention was made if the procedure required an end-to-end anastomosis be performed. With further respect to claims 32, 33, 35-38, 40, and 41, see the 102(b) rejection above for a description of similar limitations.

With further respect to claims 3 and 34, Gifford discloses inserting a tubular member into a conduit and advancing a tubular member through a vessel (see 102(b) rejection above), wherein the inserting is performed before the advancing. The applicant has not disclosed that performing the inserting after advancing provides an advantage, is used for a particular purpose, or solves a stated problem over inserting before

advancing. Furthermore, the applicant discloses that the inserting step may be performed either before or after the advancing step. It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the inserting after the advancing as a matter of design choice, since it appears both steps would perform equally well and a mere reversal of these steps involves only routine skill in the art.

With further respect to claims 14 and 42, Gifford discloses that if the blood flow through the tubular member is insufficient, oxygenated fluid may be injected through a luer fitting connected to the tubular member (for example, see column 66, lines 8-13). One of ordinary skill in the art would recognize that insufficient blood flow may be related to an insufficient, or low, blood pressure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the fluid through the tubular member at a pressure higher than the patient's blood pressure in a procedure in which blood flow through the tubular member is insufficient. Doing so would ensure the fluid passes through the tubular member and into the blood vessel.

With further respect to claims 15 and 16, Gifford discloses the fluid may be injected at a certain pressure into the tubular member, but fails to disclose the means with which the fluid is injected. However, one of ordinary skill in the art would recognize that some sort of injection means would be required to perform the injection step. By the applicant's own admission, spring-loaded, pressure limited syringes are well known in the art and further discloses that other pressurized blood sources may also be used (for example, see page 15, line 19 through page 16, line 2). Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to utilize a spring-loaded pressure limited syringe to perform Gifford's injection step in order to ensure the fluid passes through the tubular member and into the blood vessel. Furthermore, bulbs are also well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made as a matter of design choice to utilize a bulb for providing the oxygenated fluid through the tubular member, since the applicant has not disclosed that a bulb provides an advantage, is used for a particular purpose, or solves a stated problem over syringes and it appears a syringe and a bulb would perform equally well.

With further respect to claim 17, it would have been obvious to one having ordinary skill in the art at the time the invention was made to inject the fluid pressure by a bulb through a port into the tubular member that is distinct from the proximal end as a matter of design choice, since the applicant has failed to disclose such a configuration provides an advantage, is used for a particular purpose, or solves a stated problem, and it appears injecting the fluid through a port in the proximal end (as disclosed by Gifford) would perform equally well.

Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. as applied to claims 1 and 32 above, and further in view of Booth (U.S. Patent No. 5,505,698). Gifford discloses a liquid other than the oxygenated liquid flow is utilized to expand a weakened wall region of the distal region of the tubular member, thus fails to disclose the step of expanding occurs by forcing the oxygenated fluid under pressure through the tubular member. Booth discloses a tubular

member (14) comprising a flow restrictor (124; for example, see column 3, lines 20-24) and a weakened wall region (120) proximal and distal of the flow restrictor (for example, see Figure 7). Booth teaches a step of expanding that includes forcing oxygenated fluid (for example, see column 8, lines 8-10) under pressure through the tubular member to expand the weakened distal region (for example, see column 11, lines 15-33) in order to render inflation of the weakened region automatic. It would have been obvious to one having ordinary skill in the art to form Gifford's device such that the step of forcing the oxygenated fluid through the device expands the weakened distal regions as taught by Booth. Doing so would automatically expand the weakened distal region as oxygenated fluid is provided therethrough, thus reducing the number of method steps required to perform the procedure.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. as applied to claim 1 above, and further in view of Amor et al. (U.S. Patent No. 6,059,809). Gifford discloses the claimed invention except for the step of inserting a stiffening member within the tubular member. Amor discloses a method (see entire document) comprising the steps of inserting a tubular member (4) through a conduit (8) and into a vessel. Amor teaches inserting a stiffening member (6) within the tubular member (4) in order to serve as a guide through the vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert a stiffening member within Gifford's tubular member. Doing so would provide a means for guiding the tubular member through the vessel, thus preventing inadvertent damage to the blood vessel wall by the tubular member.

Allowable Subject Matter

Claim 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: the prior art fails to disclose or suggest, in combination with other limitations in the claims, withdrawing [retracting] the tubular member through the conduit and further providing the oxygenated liquid through the tubular member and into the conduit proximal region. The prior art simply disclose or suggest fixedly joining the conduit to the blood vessel, then stopping liquid flow through the tubular member, and finally withdrawing [retracting] the tubular member from the blood vessel through, and out of, the conduit.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent No.'s 5,947,919 (Kreuger et al.), 6,626,872 B1 (Navia et al.), and 5,868,764 (Rosengart) all disclose a method for joining a blood conduit to a blood vessel wall while providing an oxygenated flow through the blood vessel during the anastomosis procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Examiner, Art Unit 3773
July 30, 2009